RF 1-28-88

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 28 1988

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM: PP#7H5529 (RCB #3016). Vinclozolin (Ronilan®) on Grapes. Amendment dated 11/5/87 concerning a Processing Study. Accession #404032-01.

FROM: Nancy Dodd, Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Lois A. Rossi, PM #21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

Note: This review is expedited at the request (dated 11/20/87) of Edwin Tinsworth, Director, Registration Division.

BASF Corporation has now submitted an amendment to PP#7H5529 concerning the tolerances which are established until 5/13/88 for combined residues of the fungicide vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in or on grapes at 6.0 ppm, raisins at 30.0 ppm, and dry grape pomace at 42.0 ppm. The amendment consists of a letter dated 11/5/87 and a grape processing study titled "Magnitude of the Residue of Vinclozolin in Grape Process Fractions", R.C. Paulick, BASF Document #87/5051, p. 49, Sept. 1987. This amendment was submitted in response to RCB's reviews of PP#1E2457/FAP#7H5529 dated 2/3/87 and 12/29/86 (C. Deyrup) which required submission of a grape processing study.

In RCB's 2/3/87 review of Amendment 1/9/87 to PP#1E2457, it was recommended that the proposed tolerances for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety be established on grapes (6 ppm), dry grape pomace (42 ppm), and raisins (30 ppm). From this use, it was possible for grapes, grape concentrate, and raisins containing vinclozolin residues to be imported from Chile into the United States. The 30 ppm

vinclozolin tolerance on raisins was calculated. Thus, the petitioner was advised to submit processing data as soon as possible in order to maintain continued use. Otherwise, the import tolerance on grapes from Chile would expire in one year.

Summary of Deficiencies Remaining to be Resolved for this Use on Imported Grapes

None

Conclusions with Regard to this Amendment

1. Adequate grape processing data have been submitted. The submitted processing data indicate that the previously calculated raisin tolerance of 30 ppm is appropriate.

2. The published tolerances with expiration date for vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will adequately cover vinclozolin residues in or on grapes (6.0 ppm), raisins (30.0 ppm), and dry grape pomace (42.0 ppm). They should be established on a permanent basis.

3. Adequate validation data (recoveries, limit of quantitation) have been provided for vinclozolin and its metabolites in grape fractions (wet and dry pomace, etc.).

Recommendations

If TOX and EAB considerations permit, RCB recommends for a permanent tolerance for vinclozolin on grapes under a separate subsection of 40 CFR 180.380 as this would reflect the residue data submitted. However, before the establishment of any domestic (U.S.) tolerances on crops involving feed items, those issues outlined under "Other Considerations" that follow in this review must be resolved. The petitioner should be informed.

DETAILED CONSIDERATIONS

Deficiency

A grape processing study is needed. The tolerances on grapes, raisins, and dry grape pomace will expire on 5/13/88 unless processing data show that the tolerances will not be exceeded.

Petitioner's Response to the Deficiency

The petitioner has submitted a grape processing study. To obtain samples, two residue studies were conducted in CA using Ronilan® Fungicide, either the Flowable formulation (EPA Reg.# 7969-62) or the 50% Wettable Powder formulation (EPA Reg. # 7969-53). Five applications were made at the rate of 1.0 lb. a.i./A. A PHI of 4 days was observed. Three grape samples were harvested at maturity and processed. To obtain raisins, grapes were dried in the field and processed at a small scale raisin plant. The processing of grapes to juice and pomace in the laboratory mimicked commercial wine making practices.

Samples were stored frozen at <-5° C for 23 months between harvest and analysis. The analytical method was BWC Agricultural Chemicals Method #25F. The limit of quantitation was 0.05 ppm for grapes, juice and wet pomace and 0.10 ppm for dry pomace, raisins, and raisin waste. Recoveries for vinclozolin and its metabolites from grapes and grape processing fractions are tabulated below:

Matrix	Fortification (ppm)	Recoveries (%)
grapes	0.05	96
	20.0	96
grape juice	0.05	112
	20.0	110
wet pomace	0.05	86
	10.0	72
dry pomace	0.10	73
	15.0	80
raisins	0.10	77
	15.0	107
raisin waste	0.10	128
	15.0	89

Residues found in grapes and grape processing fractions and the concentration factors are tabulated below:

Matrix	Residue Range (ppm of vinclozolin equivalents)	Concentration Factor (from grapes)
grapes	0.84- 2.5	----
grape juice	0.44- 1.1	0.44-0.52
wet pomace	1.4 - 3.7	1.2 -1.7
dry pomace	2.9 -13.2	3.5 -5.3
raisins	2.0 - 4.8	1.8 -2.7
raisin waste	3.1 - 8.5	2.9 -3.7

RCB's Conclusions regarding the Grape Processing Deficiency

After reviewing the previously submitted grape processing study and the grape processing study submitted in this amendment, RCB concludes that adequate grape processing data have been submitted. The submitted processing data indicate that the previously calculated raisin tolerance of 30.0 ppm is appropriate. RCB also concludes that adequate validation data (recoveries, limit of quantitation) have been provided for vinclozolin and its metabolites in grape fractions (wet and dry pomace, etc.). RCB also

concludes that the published tolerances with expiration date for vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will adequately cover vinclozolin residues in or on grapes (6.0 ppm), raisins (30.0 ppm), and dry grape pomace (42.0 ppm). They should be established on a permanent basis. If TOX and EAB considerations permit, RCB recommends for a permanent tolerance for vinclozolin on grapes under a separate subsection of 40 CFR 180.380 as this would reflect the residue data submitted. However, before the establishment of any domestic (U.S.) tolerances on crops involving feed items, those issues outlined under "Other Considerations" below must be resolved.

Other Considerations

1. The following deficiencies must be resolved before establishment of domestic (U.S.) tolerances on crops involving feed items:

   a. For the proposed use, the nature of the residue in animals is not adequately understood.

      Note on Animal Metabolism: Since RCB's review of PP#1E2457 dated 4/27/81, RCB has further discussed the nature of the residue in animals in connection with PP#5F3237/FAP#5H5465 (M. Firestone, 6/28/85) and FAP#7H5531 (C. Deyrup, 3/10/87 and 9/3/87, and N. Dodd, 1/6/88). RCB concluded that the nature of the residue in ruminants and poultry is still not adequately understood.

   b. A method trial for vinclozolin and its metabolites in animal commodities (meat, milk, poultry and eggs) will be needed.

      Note on Analytical Method for Animal Commodities: Since RCB's review of PP#1E2457 dated 4/27/81, RCB has further discussed the analytical method for animal commodities (PP#5F3237/FAP#5H5465, M. Firestone, 6/28/85, and PP#5F3237 and FAP#7H5531, C. Deyrup, 3/10/87 and 3/25/87). RCB requested that the petitioner submit complete detailed analytical procedures for quantitating the appropriate residues in meat, milk, poultry, and eggs which RCB will in turn submit to EPA's Beltsville laboratory (ACS, BUD) for a method trial."

   c. The petitioner needs to submit a large animal (lactating ruminant) and poultry feeding studies. Without these data, RCB cannot predict whether there will be any problems with secondary residues in meat, milk, poultry, and eggs. (Note: No tolerances have been established for animal commodities. Tolerances for animal commodities have been proposed in connection with PP#5F3237/FAP#5H5465.)

      Note on Meat, Milk, Poultry, and Eggs: Since RCB's review of PP#1E2457 dated 4/27/81, RCB has further discussed this

issue (PP#5F3237, 6/28/85). RCB found the available feeding studies to be inadequate. RCB indicated that the petitioner would need to conduct new feeding studies on ruminants and poultry. A dairy cow feeding study should involve a group of cows at each of three feeding levels (1X, 3X, and 10X) and a control group. Each group would consist of at least 3 cows. Samples should not be pooled. The cows should be sacrificed within 24 hours of the last dose. The poultry feeding study should involve a group of laying hens at each of 3 feeding levels (1X, 3X, and 10X) and a control group. Each group of hens should consist of at least 10 hens. The hens should be sacrificed within 24 hours of the last dose. Analyses should be performed on samples from pooled subgroups of birds (ie. 3 different tissue/egg samples reflecting each of 3 feeding levels plus controls should be analyzed at a minimum).

The following tolerances on animal commodities have been proposed in connection with PP#5F3237/FAP#5H5465:

	ppm
milk	0.05
cattle, meat	0.05
cattle, fat	0.10
cattle, kidney	0.30
cattle, liver	0.70
eggs	0.10
poultry, meat	0.05
poultry, fat	0.05
poultry, kidney	0.20
poultry, liver	0.10
poultry, skin	0.10

RCB made the following additional comments in connection with PP#5F3237/FAP#5H5465 (M. Firestone, 6/28/85):

"Since animal feeds associated with the proposed use can be fed to goats, horses, sheep, and swine, tolerances for residues in meat, fat, and meat by-products of these animals should also be proposed in a revised Section F. Also, tolerances should be proposed which cover residues in meat by-products of cattle, horses, goats, sheep, hogs, and poultry. Only if residue levels in kidney and/or liver are much higher than other meat by-products should separate tolerances be proposed for these tissues."

2. An International Residue Limits (IRL) Status sheet is attached. No Canadian or Mexican limits have been established for vinclozolin on grapes. However, a Codex proposal exists for the sum of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety on grapes at 5 ppm. This Codex proposal is not numerically compatible with the U.S. tolerance on grapes of 6.0 ppm.

Attachment: International Residue Limit Status Sheet

cc: RF, SF, Circu, Reviewer-N.Dodd, PP#1E2457/FAP#7H5529, PM #21, TOX, PMSD/ISB-Eldredge
RDI:JHOnley:1/25/88:K.Arne:1/25/88
TS-769C:RCB:CM#2:RM800D:X1681:N Dodd:N Dodd:1/26/88

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Vinclozolin (Ronilan®)

CODEX NO. 159

J. Lee 1/21/88

CODEX STATUS:

☐ No Codex Proposal Step 6 or above

Residue(if Step 8): Sum of vinclozolin and metabolites containing 3,5-dichloroaniline, expressed as vinclozolin

Crop(s)	Limit (mg/kg)
grapes	5 ppm

PROPOSED U.S. TOLERANCES:

Petition No. 1E2457/7H5529

RCB Reviewer N. Dodd

Residue: vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety

Crop(s)	Limit (mg/kg)
grapes	6.0
raisins	30.0
dry grape pomace	42.0

CANADIAN LIMITS:

☑ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

Form revised 1986